IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, Plaintiffs, v MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants	)	Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

ACS'S RESPONSE TO MEDTRONIC'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Anne S. Gaza (#4093)
gaza@rlf.com
RICHARDS, LAYTON & FINGER
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7509
Attorneys for Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation

OF COUNSEL:
J. Michael Jakes
Gerald F. Ivey
Michael A. Morin
FINNEGAN, HENDERSON, FARABOW GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
(202) 408-4000
(202) 408-4400

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I. NATURE AND STAGE OF THE PROCEEDINGS

On February 18, 2005, the jury in this case found that ACS's '154, '167, '168, and '133 patents were infringed by Medtronic's MicroStent II, GFX, GFX2, GFX2 5, S540, S660, S670, BeStent2, S7, Driver, MicroDriver, and Racer stents and that those patents were not invalid for obviousness (D I 629) On April 18, 2005, Medtronic filed, *inter alia*, a renewed motion for judgment as a matter of law (JMOL) on the issues of infringement and validity (D I 651, 654) This brief responds to Medtronic's renewed JMOL motion

II. SUMMARY OF ARGUMENT

1 Substantial evidence supports the jury's finding that the infringing Medtronic stents have "cylindrical elements," each comprising an "undulating pattern" as properly construed by the Court There is no requirement that cylindrical elements have a combination of U-shaped, W-shaped, and Y-shaped members, as Medtronic contends But, even if there were, the jury still would have found infringement because it found that the welds of Medtronic's stents "extend between" adjacent rings, necessarily forming a "Y" structure

2 Substantial evidence supports the jury's finding that the infringing Medtronic stents have "connecting elements," as properly construed by the Court The evidence clearly showed that Medtronic's welds have a length and, therefore, extend between adjacent rings

3 Substantial evidence supports the jury's finding that the infringing Medtronic stents have cylindrical elements with a "length less than diameter" (L<D), as properly construed by the Court The L<D requirement is not limited to the crimped state as Medtronic now contends but, instead, may be met in any state

4 The "timing" issue raised by Medtronic does not constitute grounds for JMOL At trial, ACS proved by preponderance of the evidence that each of Medtronic's products meets the limitations of the asserted claims, as properly construed by the Court It is undisputed that all of

the accused stents were manufactured and sold in the U S , and the evidence showed that each infringes at least one of the asserted patents-in-suit Thus, infringement liability was established for each and every accused Medtronic stent The timing of when each stent was discontinued *after* it began infringing ACS's patents relates to damages, and that issue will be fully addressed in the damages trial

5 Substantial evidence supports the jury's finding that ACS owns all of the Lau patents-in-suit Medtronic failed to identify ownership as a disputed issue of fact before trial and, during trial, failed to rebut ACS's *prima facie* evidence of ownership, namely the assignment to ACS on the face of each of the Lau patents

6 Substantial evidence supports the jury's verdict that the asserted Lau claims are not invalid for obviousness

III. STATEMENT OF FACTS

A. Prosecution of the Lau Patents

ACS filed the original '558 Lau application on October 29, 1991 (AX-8 at LJA 0091) The original disclosure was substantially identical to that of the four Lau patents-in-suit, except it did not include a discussion of projecting edges That discussion was added later in the '154 continuation-in-part application

Like the patents-in-suit, the original Lau application described a stent comprising "a plurality of cylindrical elements" that are "dimensioned so as to be longitudinally shorter than their own diameters" (*Id* at LJA 0100) and preferably have "a circumferentially undulating pattern, e g , serpentine " (*Id* at LJA 0101) The applicants also explained in their original application that the "undulating pattern" can be varied to achieve different desired mechanical properties:

> The properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 12 FIG 11 illustrates an alternative stent structure in which the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements The particular pattern and how many undulations per unit of length around the circumference of the cylindrical element 12, or the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent such as radial stiffness

(*Id.* at LJA-0109) Thus, as explained above (and in the four patents-in-suit), the "undulating pattern" can either be in-phase or out-of-phase and can have different amplitudes and undulations per unit length, depending on the desired properties of the stent Some of these differences are illustrated in Figures 5 and 11 of the Lau specification, where Figure 11 depicts an "alternate undulating pattern," i e , one that is out-of-phase rather than in-phase [1]

The original Lau application made no mention of U-shaped, W-shaped, or Y-shaped members Indeed, contrary to Medtronic's assertion that "cylindrical elements" necessarily include a combination of U's, W's, and Y's, the original claims recited "cylindrically shaped elements" comprising an "undulating pattern" without *any* mention of U-, W-, or Y-shaped members (*Id.* at LJA 0115) Likewise, during prosecution of the original '558 Lau application and the subsequent '986 continuation application, there was never any discussion about U-, W-, or Y-shaped members

On July 28, 1994, ACS filed the '790 continuation-in-part application that ultimately issued as the '154 patent The '154 specification included all of the information included in the original '558 application but also expounded upon the "projecting edges" feature of the

[1] Medtronic asserts that "[t]he 'wavelike' portions of Figure 5 and Figure 11 are *the same sinusoidal pattern*," (D I 654 at 6, emphasis added), but they clearly are not A cursory comparison reveals that, in addition to having different phases, the patterns also have differently shaped valleys

invention. The applicants drafted eleven new claims (1-11) directed, in part, to the projecting edges feature. (*Id.* at LJA 1431-33, 1530.) They also "carried over" thirteen claims (12-24) from the '986 parent application and continued prosecuting those claims by adding a new limitation that the stent, upon expansion, "retains its overall length without appreciable shortening." (*Id.* at LJA-1530-31.) The latter group of claims, eleven of which ultimately issued as claims 12-22 of the '154 patent, had nothing to do with "projecting edges."

In explaining the projecting edges feature of the invention, the applicants added the following passage to the "Summary of the Invention" section:

> During expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

(AX-1, col. 2:46-52.) No language was added to the "Summary of the Invention" concerning U-, W-, or Y-shaped members. Nor were any changes made to the original descriptions of "cylindrical elements" (*id.*, col. 1:59-64) and "undulating pattern" (*id.*, col. 2:24-27). Thus, for example, the applicants continued to describe an "undulating pattern" as a "waveform" that could be serpentine:

> The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention *generally circumferential undulating pattern, e.g., serpentine*
>
> * * *
>
> The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a *waveform* which result from decreasing the *waveform's* amplitude and frequency.

(*Id.*, col. 2:24-27, 35-38, emphasis added.)

The applicants confined the remainder of their "projecting edges" discussion to the "Detailed Description of the *Preferred* Embodiments" section, where other preferred examples

of the invention were discussed. In particular, they focused their discussion on the example shown in Figures 4 and 12-14:

> In keeping with the invention, *and with reference to FIGS. 4 and 12-14*, cylindrical elements 12 are in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. Serpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members

(*Id.*, col. 6:8-16, emphasis added.) As denoted in that passage, the applicants discussed U-, W-, and Y-shaped members *only* in conjunction with the specific example shown in Figures 4 and 12-14. Because that example was one way to practice the Lau invention, it was said to be "[i]n keeping with the invention."[2]

As mentioned above, only claims 1-11 of the '154 application contained the "projecting edges" limitation. (AX-11 at LJA 1431-35.) Within that group of claims, three dependent claims (5-7) additionally required the presence of U-, W-, and Y-shaped members. As originally filed, those claims read as follows:

> 5. The stent of claim 4, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, some of said U-shaped, Y-shaped, and W-shaped members being interconnected.
>
> 6. The stent of claim 5, wherein at least some of said plurality of U-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.
>
> 7. The stent of claim 5, wherein at least some of said plurality of U-shaped, W-shaped, and Y-shaped members tip radially

[2] The applicants used similar language to describe other examples in the patent. (*See, e.g.*, AX-1, col. 4:20-21 ("FIG. 1 illustrates a stent 10 *incorporating features of the invention*."), col. 5:52-54 ("FIG. 10 illustrates a stent *of the present invention*.").)

> outwardly to form said outwardly projecting edges upon radial expansion of said stent

(*Id.* at LJA 1432.) These were the only claims of the '154 application that ever recited U's, W's, and Y's.[3]

In the first office action in the '154 prosecution, the examiner rejected claims 3 and 5-7, under 35 U.S.C. § 112, as failing to satisfy the written description requirement:

> With respect to the recitation of claim 3, no specific distances have been disclosed for the outwardly projecting edges, nor any minimum distance which would enable the edges to embed in the vascular wall.
>
> With respect to claims 5-7, although the cylindrical elements are disclosed as having U-, Y-, and W-shaped members, it is not apparent what applicant considers the connecting elements if the cylindrical elements included such shaped members because it appears that the Y-, and W-shaped members are nothing more than part of the normal serpentine pattern and further including the connecting element attached thereto (particularly, the Y-shaped members)

(*Id.* at LJA 1459-60.)

Regarding claims 5-7, the examiner expressed confusion as to whether the Y-shaped and W-shaped members were *entirely* incorporated into the "cylindrical elements" structure recited in claim 1 because, if they were, the presence of "connecting elements" (also recited in claim 1) seemed redundant. The examiner noted that the Y-shaped and W-shaped members appeared to be a composite of two *different* structures. (1) part of the "normal serpentine pattern" of the cylindrical element and (2) a connecting element. Thus, contrary to Medtronic's suggestion that "the Examiner concluded that an undulating pattern made up of *only* U-shaped members cannot be an undulating pattern" (D.I. 654 at 10), the Examiner actually concluded just the opposite

[3] Likewise, in the issued '154 patent, only dependent claims 5-7 recite U-shaped, W-shaped, and Y-shaped members. ACS did not assert those claims in this case.

Namely, he concluded that the "normal serpentine pattern" did not fully incorporate the Y- and W-shaped members because those members were actually composed of "part of the normal serpentine pattern *and further including* the connecting element attached thereto" (AX-11 at LJA 1559-60.) In other words, the "normal serpentine pattern" consisted solely of U-shaped members, and the Y- and W-shaped members were created by *adding* a connector to a U-shaped member

In response to the examiner's written-description objection, ACS amended dependent claim 5 to read as follows:

> 5 The stent of claim 4, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, *whereby a portion of said Y-shaped members forms said plurality of said connecting elements.*

(*Id.* at LJA 1534.) The applicants explained that claim 5 was amended to "define the connecting elements as a portion of the Y-shaped members, as was suggested by the Examiner" (*Id.* at LJA 1535.) They further stated that, "[a]s is clear, the tail portion of the Y-shaped member is the connecting element between the cylindrical elements" (*Id.*) Thus, the applicants left no doubt that a Y-shaped member does *not* exist solely within an undulating or serpentine pattern (as Medtronic argues) but, instead, consists of two separate parts: (1) a portion of an undulating pattern and (2) a connecting element

In response to the examiner's rejection of claim 3, the applicants deleted the requirement that projecting edges "extend *a distance* from said outer wall surface sufficient enough to embed in the vascular wall of the body lumen " (*Id.* at LJA 1431, emphasis added.) They instead rewrote the claim to require only that the projecting edges extend "radially outwardly" so as to embed in the vascular wall. (*Id* at LJA 1533-35.) Because the examiner's rejection had been based on 35 U.S.C. § 112, paragraph 1, the applicants needed only to demonstrate that their

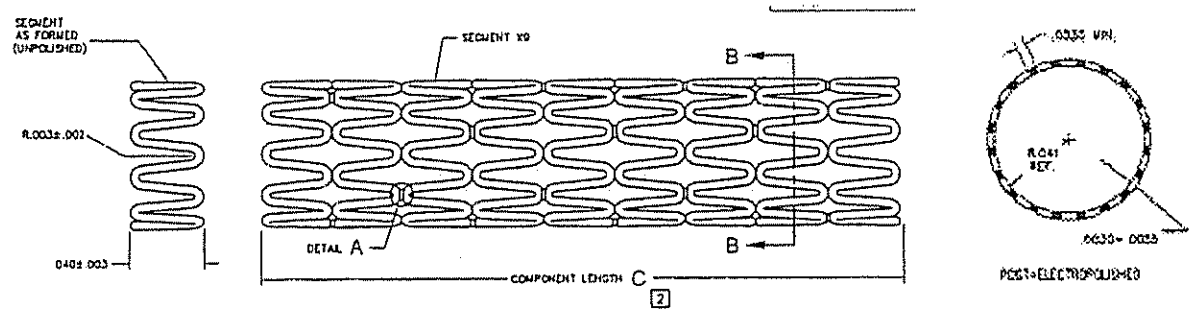
proposed claim language was supported by at least one example in the specification They did so by pointing to the particular example disclosed in Figures 4 and 12-14 and described on pages 10-11 of the application (*See id.* at LJA 1534-35) Although Medtronic contends that, by pointing to that specific example, the applicants *defined* their invention as including U's, W's, and Y's, there is no indication that the applicants were doing anything more than responding to a written-description rejection in the conventional manner, i e , by pointing to an *example* in the specification

B. The Infringing Medtronic Stents

The infringing stents in this case are Medtronic's MicroStent II, GFX, GFX2, GFX2 5, S540, S660, S670, S7, Driver, MicroDriver, Racer, and BeStent2 At trial, ACS introduced considerable evidence about each of these stents, including design specifications, photographs, results of a dimensional inspection, Medtronic's FDA submissions, marketing and educational literature, and excerpts from the Handbook of Coronary Stents

There was no dispute at trial that Medtronic's design specifications (AX-104, -105, -106, -107, -108, -109, -111, -113, -115, -116, -119A) accurately describe the structure of each of the infringing Medtronic stents Mr Allen—a Medtronic stent engineer—testified that, except for a "very small amount of information," the design specifications contain virtually every dimension needed to manufacture the Medtronic stents (Tr at 842-43)

There was no dispute at trial that each of the infringing Medtronic stents comprises a plurality of sinusoidal elements connected together, as shown below for the S7 stent



Details from S7 design specification

There was also no dispute that each sinusoidal element has a circumferential "wavelike pattern," as required by the Court's claim construction. Medtronic's expert, Dr. Vito, confirmed that fact.

> Q. But I'm asking you. Under ACS's proposed construction of undulating, you agree that all of these products would satisfy that definition?
> A. They are wave-like structures

(Tr. at 1068-69.)

Regarding the requirement that cylindrical elements have a length less than diameter ("L<D"), Dr. Segal testified—based on Medtronic's design specifications—that all of the infringing Medtronic stents except the MicroStent II are manufactured to have L<D. (*See* Tr. at 529-30.) Moreover, he testified that all of the infringing stents, including the MicroStent II, have L<D in the expanded condition. (*See* Tr. at 476-77.) Those facts were not disputed at trial.

Most of the dispute at trial centered on the "autogenous" welds of Medtronic's stents.[4] The dispute was twofold. First, the parties disputed whether Medtronic's autogenous welds are "connecting elements" that "extend between" adjacent rings, as required by the court's construction of the '154 claims. Second, the parties disputed whether the autogenous welds form "Y-shaped members," which would have been required under *Medtronic's* proposed construction.

[4] All of the infringing Medtronic stents have welds except the BeStent2, which is cut from a tube.

(but which the Court ultimately rejected) Both of those disputes boiled down to the same factual question, namely, whether Medtronic's autogenous welds have a *length*

Regarding the "extend between" requirement, Mr Allen (a Medtronic stent engineer) testified that Medtronic's welds cannot "extend between" adjacent rings because the welds have no length (*See* Tr at 796 ("[T]hey are rigid because they don't have any length They don't -- they don't extend between anything "), *see also* Tr at 839-840, 853) With respect to whether Medtronic's welds form a "Y-shaped member," Dr Vito (Medtronic's infringement expert) similarly made clear that the issue was whether the welds have a *length* (Tr at 1096)

The evidence presented at trial showed that the welds of Medtronic's infringing stents are three-dimensional, i e , they take up space and have a *length*, width, and thickness (*See* Tr at 1055) Each of Medtronic's design specifications conveys this information in "Detail A," which depicts a weld annotated with minimum dimensions (*See* Tr at 849-50; see also AX-104, -105, -106, -107, -108, -109, -111, -113, -115, -116, 119A) Also, it was undisputed that Medtronic performs "dimensional inspections" of its stents, which include verifying "weld width and *weld length* " (AX-293a at 16; *see also* Tr at 853, 1057)

Medtronic's welding process is "autogenous," meaning that no new material is added during the process Nevertheless, the process results in a *new* structure called a "weld," which is created from metal borrowed from each of the adjacent crowns As Medtronic's stent engineer, Mr Allen, explained:

> Q All right The crowns come together The heat is applied Some of the metal from one crown and some of the metal from the other crown come together, and they form something new, called the weld?
> A They mix together and form an autogenous fusion weld
> Q Which is new, because you didn't have a weld before?
> A It's new that they're connected now

Q And the weld itself is new because it wasn't there before, correct?
A The material that -- yes That's correct

(Tr at 854)

Based on Medtronic's design specifications and his own observations, Dr Segal testified that the welds of Medtronic's products constitute "connecting elements" that "extend between" adjacent rings, as required by the Court's construction of claims 1, 4, and 12 of the '154 patent (Tr at 547-550) He also testified that, under Medtronic's proposed construction of "cylindrical element" (i e , requiring a combination of U-, W-, and Y-shaped members), the accused Medtronic stents (other than the BeStent2) would still infringe the Lau patents because they all contain Y-shaped members, i e , where the welds attach to the undulating rings (Tr at 559-61)

IV. ARGUMENT

A. JMOL Standard

A post-verdict motion for JMOL "should be granted only where there is no legally sufficient basis for a reasonable jury to have found for the non-moving party" *Price v. Delaware Dept. of Correction*, 40 F Supp 2d 544, 549 (D Del 1999) (citing *Garrison v. Mollers N. Am., Inc.*, 820 F Supp 814, 818-19 (D Del 1993)) In reviewing a renewed JMOL motion, the court must "consider the evidence in the light most favorable to the nonmoving party and afford the nonmoving party the benefit of all logical inferences" *Boyce v. Edis Co* , 224 F Supp 2d 814, 816 (D Del 2002) (citing *Keith v. Truck Stops Corp. of America*, 909 F 2d 743 (3d Cir 1990)) "The movant has a difficult burden" *Id.* at 816 If the "record contains the minimum quantum of evidence from which a jury might reasonably afford relief" then the reviewing court must deny the motion *Keith,* 909 F 2d at 745 (quoting *Smollett v. Skayting Dev. Corp* , 793 F 2d 547 (3d Cir 1986))

B. Substantial Evidence Supports the Jury's Finding That All of the Infringing Medtronic Stents Have an "Undulating Pattern"

1. The Court Properly Construed "Undulating Pattern" and the Jury Properly Found Infringement Under That Construction

Medtronic contends the Court erred in construing "undulating pattern" (and therefore "cylindrical element") as requiring only a "wavelike" pattern. According to Medtronic, the proper construction of "undulating" requires a combination of two or more of the following shapes: U-shaped, W-shaped, and Y-shaped members. That proposed construction is incorrect, however, because it ignores the Federal Circuit's claim-construction guidelines and the record in this case.

Claim construction begins with the words of the claim, which are presumed to have their ordinary meaning. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("[w]e indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning."). If a claim term is clear on its face, then "consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). An intent to deviate from the ordinary meaning of a claim term can be signified by the patentee's "redefining the term or characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313 (Fed. Cir. 2002).

Medtronic does not dispute that the ordinary meaning of "undulating" is wavelike. Indeed, Dr. Vito acknowledged that fact at trial:

> Q I'm asking you about ordinary meaning that anybody can look in a dictionary and find out. You would agree, sir, that wave-like pattern is pretty close to the ordinary meaning of undulating?
> A Yes, I would agree with that.

(Tr. at 1076.) Accordingly, "wavelike" is presumed to be the correct construction of "undulating," absent a clear disavowal of that meaning in the specification or prosecution history. *See Teleflex*, 299 F.3d at 1327.

The Lau specification uses "undulating" in a manner consistent with its ordinary meaning. For instance, the specification compares the expansion of an "undulating pattern" to "changes in a *waveform* which result from decreasing the *waveform's* amplitude and frequency." (AX-1 at col. 2:35-38.) The specification also identifies a "serpentine" (i.e., smooth or curvy) pattern as one example of an "undulating" pattern. (*Id.*, at col. 2:24-27.) The figures, too, are consistent with the ordinary meaning of "undulating." (*See, e.g.*, Figs. 5 and 11, showing two different versions of a wavelike pattern.)

Medtronic argues, though, that the Figures in the Lau patent are *also* consistent with Medtronic's proposed construction because each shows a combination of U-, W-, and/or Y-shaped members. (D.I. 654 at 5-7.) That is irrelevant, however, because Medtronic's proposed construction is *contrary* to the ordinary meaning, and the figures are equally consistent with the *ordinary* meaning of "undulating," i.e., a wavelike pattern. *See Teleflex*, 299 F.3d at 1327.

Medtronic also argues that, because Figures 12-14 are described in the "Preferred Embodiments" section as having a "serpentine" pattern (which Medtronic alleges is synonymous with "undulating"), the applicants necessarily intended to redefine "undulating" as requiring U's, W's, and Y's. That argument fails, however, for at least three reasons. First, the inventors made clear in the specification that "serpentine" is merely an *example* of "undulating." (*See* AX-1 at col. 2:24-27 ("undulating pattern, *e.g.*, serpentine").) Therefore, the two terms are not synonymous, as Medtronic contends. Second, the mere fact that the inventors used the term "serpentine pattern" to describe a preferred embodiment does not mean they intended to *define*

"serpentine pattern" in that manner [5] Third, the Federal Circuit has repeatedly held that "an accused infringer cannot overcome the 'heavy presumption' that a claim term takes on its ordinary meaning simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history" *Teleflex*, 299 F 3d at 1327 Medtronic's attempt to do so should therefore be rejected

Medtronic next argues that U-, W-, and Y-shaped members are essential to the claimed invention because they ensure "spacing" between adjacent rings (D I 654 at 4-5) The "spacing" argument, however, (which Medtronic has raised repeatedly in conjunction with various claim terms, e g , "connecting element," "connected," and "weld connection") lacks merit As ACS explained during the *Markman* proceedings, the suggestion in the Lau specification that cylindrical elements be arranged close together but "not so close as to compromise the longitudinal flexibilities" is intended merely to ensure longitudinal flexibility, not some arbitrary amount of spacing between cylindrical elements Moreover, nothing in that phrase redefines "undulating" as a combination of U-, W-, and Y-shaped members using words of "manifest exclusion or restriction" *Teleflex*, 299 F 3d at 1327

Next, Medtronic contends that the prosecution history of the Lau patents dictates that "undulating" be defined as a combination of U's, W's, and Y's (D I 654 at 7-11) Specifically, Medtronic alleges that "ACS was *forced* to add U-, W-, and Y-shaped members to its specification" to secure apparatus claims in the '154 patent That, too, is false As explained above, the discussion of U's, W's, and Y's in the '154 specification was confined entirely to the

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[5] Medtronic asserts that the introductory phrase "in keeping with the invention" proves the applicants intended to limit their invention to the examples shown (D I 654 at 5, fn 3) That phrase, however, merely means that the examples are *consistent with* (i e , "in keeping with") the invention By analogy, a dark blue suit and red tie are "in keeping with" a business-attire dress code, but they do not *define* the dress code

projecting-edges feature, and only eleven of the original twenty-four pending claims in the '154 application recited "projecting edges" (AX-11 at LJA 1431-35.) Of those, only three *dependent* claims ever mentioned U's, W's, and Y's (*Id.* at LJA 1431.) Moreover, during prosecution, the applicants never attempted to distinguish any prior art based on U's, W's, and Y's, and the examiner never mentioned U's, W's, and Y's in conjunction with any prior-art rejections. Clearly, the idea of U's, W's, and Y's was not central to the prosecution or allowance of the '154 claims.

Finally, Medtronic asserts that the Examiner's Section 112 rejection of dependent claims 3 and 5-7, and the applicants' response thereto, require that U's, Y's, and W's be added to the definition of "undulating." Medtronic first points to the applicants' response to the indefiniteness and written-description rejections of claim 3. In addition to deleting the requirement that the projecting edges extend "a distance" from the outer wall (i.e., to overcome the indefiniteness rejection), the applicants also demonstrated support in the written description for claim 3 (which required projecting edges that embed in the vessel wall) by referring to a particular example in the specification. That example happened to include a "serpentine pattern 30" made up of "U-shaped, W-shaped, and Y-shaped members that tip radially outward to form a projecting edge." (AX-11 at LJA 1534-35.) Medtronic contends that, in pointing to that particular example, "ACS conceded that *all* embodiments covered by claim 3 would have some combination of these various members" and that "'serpentine pattern 30' is [necessarily part] of the cylindrical element in claim 1." (D.I. 654 at 9-10.) That is simply not so.

The "written description" requirement of 35 U.S.C. § 112, paragraph 1 requires only that there be "enough disclosure in the patent to show one of skill in [the] art that the inventor 'invented what is claimed.'" *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989,

1001 (Fed Cir 2000) (quoting *Vas-Cath Inc v Mahurkar*, 935 F 2d 1555, 1563 (Fed Cir 1991)). Written-description support for a broad claim can be provided by a single example or preferred embodiment in the specification *See, e g., In re Rasmussen*, 650 F 2d 1212 (C C P A 1981) Indeed, even "drawings alone may provide a 'written description' of an invention as required by § 112" *Vas-Cath*, 935 F 2d at 1565 Therefore, in this case, the mere fact that the applicants pointed to a particular example (i e , Figs 13-14) to overcome a written-description rejection of claim 3 does *not* mean they intended to limit claim 3 (let alone claim 1) to that exact example Medtronic's argument simply has no basis in law

Medtronic's other Section 112 arguments are similarly misguided For instance, referring to the examiner's written-description rejection of claim 5, Medtronic asserts that "the Examiner concluded that an undulating pattern made up of *only* U-shaped members cannot be an undulating pattern because there would be nothing connecting adjacent cylindrical elements" (D I 654 at 10) The examiner, however, clearly concluded just the opposite:

> [I]t appears that the Y-, and W-shaped members are nothing more than part of the normal serpentine pattern and **further** including the connecting element attached thereto (particularly, the Y-shaped members)

(AX-11 at LJA 1459-60, emphasis added) The word "further" leaves no doubt that the examiner understood the "normal serpentine pattern" *not* to include connecting elements Instead, he understood a Y- or W-shaped member as including part of the serpentine pattern (i e , a U-shaped member) and "*further including* a connecting element attached thereto" The applicants, too, understood this and amended the claims accordingly Specifically, in their response to the examiner's rejection, they made absolutely clear that the connector portion of a W- or Y-shaped member is *not* part of the "cylindrical element" recited in the claims

> As is clear, the tail portion of the Y-shaped member is the connecting element *between* the cylindrical elements It is believed that claim 5, as amended, overcomes the § 112 rejection

(*Id* at LJA 1535, emphasis added) Obviously, the tail of a Y-shaped member cannot be "*between*" two cylindrical elements and also be *part* of the cylindrical elements as Medtronic contends Medtronic's argument, therefore, cannot stand

In summary, the Court's construction of "undulating" is clearly correct because it is consistent with the ordinary meaning of "undulating" and is consistent with the claims, specification, and prosecution history of the Lau patents-in-suit

The jury properly found that Medtronic's infringing stents have an "undulating" pattern as properly construed by the Court That finding was supported by substantial evidence at trial, including the testimony of ACS's expert Dr Segal, who explained that each of the infringing Medtronic stents has an undulating (i e , wavelike) pattern (Tr at 477-78, 516, 540) That finding was also supported by the testimony of *Medtronic's* expert, Dr Vito, who conceded that Medtronic's stents all have a "wavelike" pattern (Tr at 1067-68) Finally, that finding was supported by Medtronic's design specifications, which clearly show that each of the infringing stents comprises "sinusoidal elements" having a wavelike pattern (AX-104, -105, -106, -107, -108, -109, -111, -113, -115, -116, 119A)

2. Even Under Medtronic's Proposed Construction of "Undulating Pattern," the Jury Would Have Necessarily Found Infringement

Medtronic contends, incorrectly, that its infringing stents "are made up exclusively of U-shaped members" and that "ACS does not dispute this fact" ((D I 654 at 15) Both points are flat wrong

To begin with, Dr Segal clearly testified that Medtronic's infringing stents are *not* made up exclusively of U-shaped members but, instead, also contain Y-shaped members (Tr

at 559-61) Moreover, Dr Vito made clear at trial that, as long as a connecting element has *some length*, it can form a Y-shaped member as required under Medtronic's proposed construction:

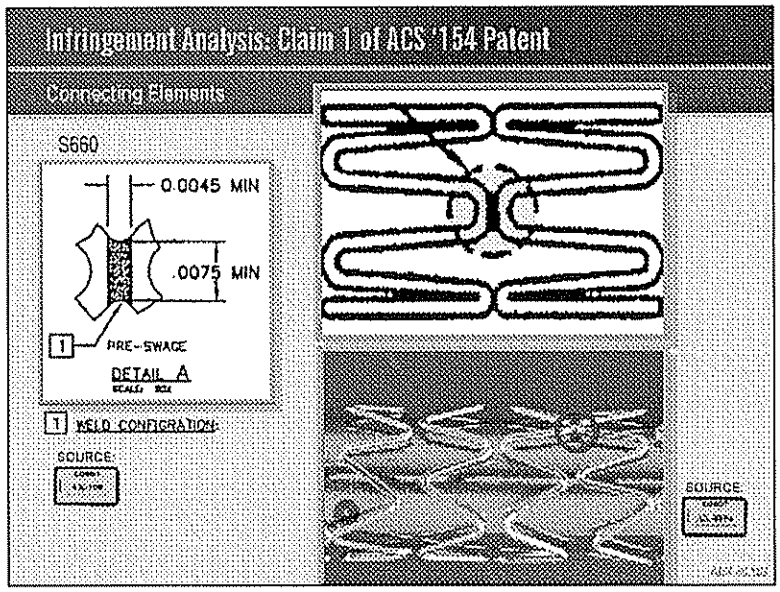
> Q And I take it it does not matter, in your opinion, that that connecting element is very, very short?
> A It can be short as long as it's got some length, that's no problem
> Q As long as it has some length, it's a Y?
> A Fair enough

(Tr at 1096) The evidence at trial clearly showed that the welds of Medtronic's stents have a length and, therefore, form a Y-shaped member where they intersect with a cylindrical element (*See, e.g.*, Tr at 559-61, 849-50, 853-54, 1059, 1096; AX-293a at 16) Indeed, the jury necessarily found that Medtronic's autogenous welds "extend between" adjacent cylindrical elements, as required by the asserted claims of the '154 patent (Tr at 1918-19) Given that finding, and given Dr Vito's testimony that a connecting element can form a Y-shaped member "as long as it's got *some* length," the jury necessarily would have found that the infringing Medtronic stents have Y-shaped members

C. Substantial Evidence Supports the Jury's Finding That the MicroStent II, GFX, GFX2, GFX2.5, S540, S660, S670, and BeStent2 Stents Have "Connecting Elements," as Properly Construed by the Court

The Court construed "connecting elements" in the '154 claims to mean "segments of a stent that extend between adjacent cylindrical elements, connecting them together " (D I 628 at 25) Based on that construction, the jury found that each of Medtronic's MicroStent II, GFX, GFX2, GFX2 5, S540, S660, S670, and BeStent2 has "connecting elements" that extend between adjacent cylindrical elements Contrary to Medtronic's assertion, that finding is supported by substantial evidence, which was presented at trial through Medtronic's own documents and witnesses, as well as through the testimony of Dr Segal

Medtronic argues that its welded stents cannot have connecting elements because they are connected by "autogenous laser fusion," which does not add any new material to the device.[6] (D I 654 at 16) Yet even Medtronic's own stent engineer, Mr Allen, conceded that the "autogenous" process results in a *new* structure—a "weld"—which is created from metal borrowed from the two adjacent crowns (Tr at 854) Dr Vito confirmed that this new weld is situated "*between* the crowns" of adjacent cylindrical elements (Tr at 971-72) At trial, the jury was given Medtronic's design specifications for each of the infringing stents (AX-104, -105, -106, -107, -108, -109, -111, -113, -115, -116, -119A) As Dr Segal explained to the jury, those specifications indicate *minimum dimensions* for Medtronic's welds (Tr at 547-48) To confirm the design specifications, Dr Segal also showed the jury actual photographs of Medtronic's welds (AX-899a), which clearly show that the welds, themselves, are three dimensional, i e , they take up space and extend between adjacent cylindrical elements.[7] (Tr at 547-50)



In addition to Dr Segal's testimony, the jury heard from Mr Allen, a Medtronic stent engineer, who confirmed that Medtronic's design specifications provide minimum dimensions

[6] Medtronic does not dispute that the BeStent2 has connecting elements

[7] Dr Vito agreed that, from the photographs, "there may be something [that] looks like it might be extending between the two" crowns (Tr at 1000) He criticized the photographs, though, because of possible lighting problems (Tr at 991-93) Yet the jury was certainly entitled to believe what they saw with their own eyes rather than Dr Vito's speculation

for the autogenous welds. (Tr. at 849-50.) Dr. Vito likewise acknowledged that fact. (Tr. at 1056.)

Dr. Vito testified that Medtronic's autogenous welds are "three-dimensional" and that they "take up space".

> Q. Is [the weld] three-dimensional?
> A. It's definitely three dimensional.
> Q. It takes up space?
> A. Takes up space.
> Q. Because --
> A. Well, it occupies space, so it has dimensions.

(Tr. at 1055.) Yet he refused to admit that the welds have a "length".

> Q. And because it's three-dimensional, that means it has three dimensions: Length, width and thickness?
> A. It's such a complex shape, it's much more than that.
> Q. Sir, three-dimensional, it means three dimensions; right?
> A. No.

(Tr. at 1055.) The latter part of Dr. Vito's testimony, however, was flatly contradicted by Medtronic's "dimensional inspection" procedure, which includes the step of inspecting stents for "weld *length*":

> The completed [GFX] stent is visually inspected to ensure the correct numbers of segments and weld pattern. A *dimensional inspection* is completed on the cross section, weld width and *weld length*.

(AX-293a at 16.) Thus, the jury could have reasonably disregarded Dr. Vito's nonsensical testimony that Medtronic's welds have no "length" since the weight of the evidence was clearly to the contrary. Likewise, the jury reasonably could have disregarded Mr. Allen's irrelevant testimony about "rigid welds" and the "transfer [of] forces from one segment to the other" (*see* D.I. 654 at 17), since that testimony had nothing to do with whether the welds extend between adjacent rings.

Medtronic contends that the jury could not reasonably have relied on Dr. Segal's testimony about "connecting elements" because he is not a welding expert. (D.I. 654 at 18.) Yet, even putting aside that Dr. Vito is *also* not a welding expert (*see* Tr. at 926; *see also* Tr. at 1034), Medtronic's assertion lacks merit. Dr. Segal runs a medical device company, Medluminal Systems, which is focused on cutting edge technology for treating problems with interventional cardiology. (Tr. at 359-60; *see also* Tr. at 373-75.) As he explained to the jury, he has been developing medical devices for nearly twenty years (*see* Tr. at 368-69) and has received numerous patents for his medical-device inventions (*id.* at 371). Before starting Medluminal Systems, he founded another medical-device company called Cardiometrics, for which he also served as R&D director. (Tr. at 372.) Dr. Segal explained that, in these medical-device companies, he works closely with engineers on an "hourly basis" and the engineers report directly to him. (Tr. at 372-73.) He further testified that he has been involved with "coming up with *blueprints* in the specifications of the products" (Tr. at 373) and that he has "reviewed *design specifications* and looked at the products to see whether they're done correctly" (Tr. at 565). In short, Dr. Segal is an "expert in the design of stents" (Tr. at 564), which includes interpreting design specifications (i.e., blueprints) for stent products.

In preparing for his testimony in this case, Dr. Segal physically examined and photographed representative samples of Medtronic's infringing stents. (Tr. at 419.) He also reviewed the design specifications for those stents. (Tr. at 423.) Based on that review, he concluded that the welds of Medtronic's products are "connecting elements" that extend between

adjacent rings.[8] (Tr. at 547-50.) The jury reasonably could have relied on that testimony given Dr. Segal's considerable experience and expertise in the medical-device field.

Medtronic also contends that "the sole basis for Dr. Segal's opinion . . . was based on magnified photographs of Medtronic's stents from marketing material." (D.I. 654 at 18.) That is false. The photographs Dr. Segal relied upon are not from "marketing material" as Medtronic contends but, instead, are photographs of the *actual* representative stent samples that Medtronic provided to ACS during discovery, which Dr. Segal personally examined. (*See* Tr. at 419-20; AX-966.) Moreover, the photographs were hardly the "sole basis" of Dr. Segal's opinion. Quite the contrary, Dr. Segal testified that the photographs merely *confirmed* what is clearly shown in Medtronic's design specifications, i.e., that the welds are three-dimensional and extend between adjacent rings. (Tr. at 419 ("The photographs that I've taken and seen are *consistent* with my findings."), *see also id.* at 547-48.)

As a last-ditch effort, Medtronic asserts that its autogenous welds cannot be connecting elements that extend between adjacent rings because they are not "*discrete* element[s] inserted or created between" the rings. (D.I. 654 at 19.) That argument fails, however, because the Court's claim construction does not require connecting elements to be "discrete," as Medtronic had originally proposed in its *Markman* briefs. Instead, the Court's claim construction requires only that connecting elements be "segments of a stent," and there was no dispute at trial that Medtronic's three-dimensional welds are segments of a stent.

[8] Inexplicably, Medtronic asserts that "Dr. Segal never pointed to a weld that '*extended between* adjacent cylindrical elements.'" (D.I. 654 at 18.) The record indicates otherwise. (*See* Tr. at 547 ("Q. And do the Medtronic products have connecting elements that *extend between* the cylindrical elements? A. Yes, they do.").)

D. Substantial Evidence Supports the Jury's Finding That All of the Infringing Medtronic Stents Have "Cylindrical Elements," Each Having a "Length Less Than Its Diameter," as Properly Construed by the Court

The Court construed "cylindrical element" to mean "a radially expandable segment of a stent having a *longitudinal length less than its diameter* ["L<D"] with a circumferential undulating pattern. Furthermore, cylindrical rings are not in and of themselves stents." (Tr. at 1883; *see also* D.I. 542 at 2-3.) Contrary to its position at trial, Medtronic now argues that the Court's claim construction requires L<D in the *crimped state*, notwithstanding that the construction is silent as to any particular state. That new claim-construction argument is both plainly wrong on the merits and highly disingenuous, given that Medtronic took precisely the *opposite* position at trial.

During the *Markman* proceedings, both parties agreed that the proper construction of "cylindrical element" required L<D. As Medtronic stated in its opening *Markman* brief, "Vascular agrees that the construction for 'cylindrical element' should include a limitation that its length is less than its diameter." (D.I. 420 at 10.) Likewise, during the *Markman* hearing, Medtronic's counsel told the Court:

> We've reviewed it, and we've all told you that both parties agree on longitudinal length less than diameter. That should be a part of cylindrical element. Agreed.

(D.I. 499 at 483.) Yet nowhere in its claim-construction briefs or in its argument to the Court did Medtronic ever suggest that L<D must be met in a *particular* state, e.g., the "crimped" state.

At trial, Medtronic argued that all of the asserted Lau claims are invalid over various prior art references. With respect to the L<D limitation, Medtronic's validity expert, Professor Saigal, told the jury that two prior-art references, Boneau '331 and Palmaz '417 (a.k.a. "spiral Palmaz"), satisfy that limitation because they disclose L<D *in the expanded state*:

Q. length less than diameter. Now, sir, going to Slide No. 58, did the Court construe that term?
A. No, it didn't.
Q. Okay. Did you look at the prior art to see if there were stents with length less than diameter?
A. Yes, I did.
Q. And what did you find?
A. I found that there were two stents that had length less than diameter that were in the prior art.
Q. Okay, sir. And if you turn to Slide No. 59, what does that show?
A. It shows that spiral Palmaz and Bonneau are the ones that both had their lengths less than their diameter *in the expanded state*.

(Tr. at 1339.) Professor Saigal specifically emphasized, again and again, that he was referring to L<D in the *expanded state* for both the spiral Palmaz and Boneau stents. (*See* Tr. at 1340 ("Again, to emphasize, this is all in the *expanded state* for this particular stent."), *see also id.* at 1341.) Thus, Professor Saigal's trial testimony directly contradicts Medtronic's new argument that L<D must be present in the *crimped* state.

Medtronic argued to the jury that all of the asserted claims of the '154, '167, and '133 claims were obvious in light of the combination of Boneau and spiral Palmaz[9] (Tr. at 1372-75, 1377-78.) Yet, as clearly established by Professor Saigal's testimony, those two references only disclose L<D (if at all) in the *expanded state*, not in the crimped state as Medtronic now asserts is required. (*See* Tr. at 1339-40; *see also* AX-18 and AX-160.) Medtronic even attempted to prove anticipation at trial by arguing (in a proffer to the Court) that "each element of each asserted claim of the '154 and '167 patents was disclosed in the prior art by the Spiral Palmaz '417 patent." (D.I. 618 at 1.) Once again, it is undisputed that Palmaz '417—which Medtronic

[9] For the '168 "weld connection" claims, Medtronic added Wolff '404 to that combination. (Tr. at 1375-77.)

told the court *just four months ago* discloses "each element" of the asserted claims—discloses L<D (if at all) only in the *expanded* state, not the crimped state.

In short, Medtronic wants to have its cake and eat it too. At trial, Medtronic was perfectly happy asserting a broad interpretation of L<D that could be satisfied in *any* state including the expanded state (i.e., as disclosed in Palmaz '417). Indeed, Medtronic did not object to the Court's jury instruction regarding the L<D requirement, which was silent as to a particular state. (*See* Tr. at 1747-50; *see also* D.I. 628 at 24.) Yet, having lost its validity arguments at trial, Medtronic now asks the Court to adopt an ultra-narrow interpretation of L<D, which can only be met in the "crimped" state. Medtronic could have raised this "crimped state" argument during the *Markman* proceedings, where the issue could have been fully ventilated in the appropriate format. That it chose not to is a tacit admission that its argument lacks merit.

This Court has held that new claim-construction arguments cannot properly be raised for the first time in a JMOL motion:

> Issues regarding claim construction are properly raised prior to the end of the trial proceedings and before a decision by the jury. "It is improper to adopt a new or more detailed claim construction in connection with the JMOL motion when issues have not been properly raised prior to jury instructions." [*Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1321 (Fed. Cir. 2003).] After providing the jury with the claim language, "it is too late at the JMOL stage to argue for or adopt a new interpretation and test the jury verdict by that new interpretation." *Id.* Where claims are in dispute after trial, a party cannot "wait until after the jury returned a verdict against it and then on JMOL request a different construction, deleting a portion that the party previously agreed to." *Abbott Laboratories v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1352 (Fed. Cir. 2003).

Genzyme Corp. v. Atrium Med. Corp., 315 F. Supp. 2d 552, 576 (D. Del. 2004). Nevertheless, in an abundance of caution, ACS will respond to Medtronic's new and untimely argument regarding "L<D."

Medtronic makes two arguments in support of its new claim-construction theory that L<D must be measured in the crimped state. First, it argues that the term "radially *expandable*" in the Court's claim construction requires L<D in the crimped state. (D.I. 654 at 20-22.) Second, it argues that L<D must be met in the crimped state because that is where "longitudinal flexibility" is most important. (*Id.*) Both arguments are wrong.

The term "expandable" does not, as Medtronic contends, constrain all the claim limitations to the crimped state. For one thing, a stent is certainly "expandable" in the as-manufactured (i.e., uncrimped) condition.[10] Indeed, the Lau specification refers specifically to the uncrimped stent in Figure 4 as being in the "*unexpanded* state." (AX-1 at col. 3:57-60.) More to the point, though, "radially expandable" is an inherent property of a stent, which is present in *all* conditions of the stent. That fact is obvious when one considers the language of claim 14 of the '154 patent, which refers to "radially *expandable* cylindrical elements in an *expanded* condition." (AX-1 at col. 9:37-39.) Under Medtronic's newly proposed theory (i.e., where "expandable" means crimped), claim 14 would be utterly nonsensical since the cylindrical elements would have to be simultaneously crimped *and* in an "expanded condition." The Federal Circuit has warned against such absurd results. *See, e.g., Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 189 F.3d 1370, 1376 (Fed. Cir. 1999) (refusing to adopt a construction that would result in an "absurd" reading of a dependent claim).

Medtronic's new "longitudinal flexibility" argument is likewise faulty. First, Medtronic improperly conflates two separate and distinct claim limitations, "longitudinally flexible" and "cylindrical elements." While flexibility is certainly important in the delivery state, that fact

[10] A stent is also still expandable even after implantation because the physician typically has the option to "post-dilate" or *further* expand the stent if conditions warrant. (*See* Tr. at 537-38.)

alone does not dictate that L<D must be measured in the delivery state, any more than it dictates that other claim limitations (e g , "projecting edges" or "non-appreciable shortening") must be satisfied in the delivery state Each limitation must be analyzed independently Moreover, Medtronic is incorrect that flexibility is important only in the crimped state To the contrary, the Lau specification emphasizes that flexibility is important in *both* the unexpanded and expanded states:

> The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure *both in the unexpanded as well as the expanded condition* These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent

(AX-1 at col 3:5-12)

Medtronic makes no attempt to support its new "crimped state" theory with a traditional claim-construction analysis, and for good reason None of the asserted independent claims in this case expressly requires that "L<D" be measured in a particular state, let alone the crimped state Based on the *ordinary meaning* of those claims, therefore, L<D can be met in any state The specification and prosecution history are fully consistent with that ordinary meaning since neither expressly states, using words of "manifest exclusion or restriction," that L<D is limited to the crimped state *See Teleflex*, 299 F 3d at 1327 The specification states only that "[t]he individual radially expandable cylindrical elements of the stent are *dimensioned* so as to be longitudinally shorter than their own diameters," without specifying a particular state (AX-1 at col 1:62-64) Because the intrinsic evidence thus gives a clear meaning to "cylindrical element" that is not limited to L<D in the "crimped" state, it would be improper as a matter of law to read "crimped" into the claims as Medtronic seeks to do *See id* at 1151-52

E. Medtronic's "Timing" Argument Is a Red Herring

Medtronic contends it is entitled to JMOL because ACS allegedly "failed to show that Medtronic made, used, sold or offered for sale *any* products during the term of the patents in suit." (D.I. 654 at 23, emphasis added.) That, of course, is a gross exaggeration. Medtronic expressly admitted in the Pre-Trial Order that *all* of the accused Medtronic products were manufactured and sold in the U.S. (D.I. 538, Ex. 1 at 3.) Moreover, that fact was manifestly evident from the testimony and exhibits admitted into evidence at trial. For instance, the four volumes of the Handbook of Coronary Stents (AX-801a, 802b, 803a, and 804a), which were admitted into evidence and discussed by Dr. Segal (Tr. at 467, 496,-97, 510-11, 527-28), clearly set forth when each of the infringing Medtronic products was placed on sale in the U.S. Likewise, the testimony of Dr. Kahn, Ms. Huss, and Mr. Allen, among others, clearly established at least that (1) the MicroStent II and GFX stents were sold commercially after 1997 (Tr. at 279, 1475); (2) the GFX II, GFX2 5, S660, and S670 were developed and sold after 1997 (Tr. at 863; AX-123); and (3) the S7 and Driver stents were commercially sold after 2001 (Tr. at 281, 291).

Medtronic does not dispute that *all* of the infringing Medtronic products were made, used, or sold after the issuance of at least *one* of the Lau patents-in-suit. Indeed, Medtronic's proffer alleges, at most, that the MicroStent II, GFX, and GFX2 stents were discontinued before the '167, '168, and '133 patents issued and the GFX 2.5 and S540 stents were discontinued before the '133 patent issued. (D.I. 654 at 27.) *All of those products*, however, were found to infringe the earlier '154 patent, and Medtronic can point to no legally sound basis for setting that verdict aside, for there is evidence in the record that each of those products was on sale in the U.S. after the issue date of the '154 patent. (*See* Tr. at 279, 863, 1475, AX-123.)

The "timing" issue raised by Medtronic really relates to *damages* rather than liability. For, even accepting Medtronic's proffer as true, *all* of the accused Medtronic products infringe at

least one of the Lau patents-in-suit. As ACS explained to the Court at trial, the reason the jury was asked to compare Medtronic's earlier infringing stents (e.g., the GFX) to ACS's later-issued claims was simply to avoid the necessity of having to try that same issue again during the damages trial. Had the jury not considered, for instance, whether the GFX stent satisfies the claims of the '133 patent, Medtronic might have argued during the damages trial that the GFX is a non-infringing alternative to its current line of infringing stents, i.e., as a way to avoid lost-profits damages. The parties then would have had to try the entire infringement issue again to a new jury. That wasteful exercise has been avoided in this case by having the first jury address *all* the issues concerning whether Medtronic's stents meet the claims of ACS's patents.

Medtronic cites the infringement statute, 35 U.S.C. § 271(a), and asserts that ACS "failed to prove every element of liability." Yet, as explained above, ACS proved that Medtronic is liable for infringement because *each* of the MicroStent II, GFX, GFXII, GFX2.5, S540, S660, S670, BeStent2, Racer, S7, Driver, and MicroDriver stents meets every limitation of at least one claim of the four Lau patents-in-suit.[11] (See Tr. at 1918-24.) Medtronic's "timing" argument does not challenge that basic fact. Instead, it focuses merely on the possibility that some of Medtronic's products may have only infringed *one* ACS patent instead of three or four. Infringement of one patent, however, is enough to establish liability.

Medtronic also ignores that one of the remedies ACS has a right to seek in this case is a permanent injunction on the manufacture of *all* of Medtronic's infringing stents, including those

[11] The Federal Circuit has repeatedly held that "[d]etermining infringement is a two-step process. First, the court determines the scope and meaning of the asserted claim. Then, the court compares the properly construed claims with the accused device or product to reach a finding regarding infringement." *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1371 (Fed. Cir. 2004). Since both prongs of that infringement analysis were performed in this case, the jury properly reached "a finding regarding infringement" in accordance with the Federal Circuit's guidelines.

that are currently discontinued The law is clear that a permanent injunction is not limited to just current products but, instead, may extend to discontinued products that might infringe in the future *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281-82 (Fed. Cir. 1988) ("The fact that the defendant has stopped infringing is generally not a reason for denying an injunction against *future* infringement . . .") (emphasis added)[12] Accordingly, ACS was entitled to prove—and indeed did prove—that any future manufacture of Medtronic's discontinued stents (e.g., the GFX) would infringe not only the earlier '154 patent but also the '167, '168, and '133 patents.

Medtronic's Seventh Amendment argument lacks merit. Medtronic cites no authority for its assertion that "infringement liability is a single, discrete issue and must be determined by a single jury." (D.I. 654 at 24.) Indeed, the case Medtronic relies upon, *In re Paoli R.R. Yard PCB Litig.*, 113 F.3d 444 (3d Cir. 1997), clearly supports the opposite proposition. In *Paoli*, the Court held there was no Seventh Amendment violation in allowing a first jury to determine whether the plaintiffs had been exposed to PCBs and a second jury to determine whether the defendants' conduct caused that exposure. *Id.* at 452 n.5. Though those two issues formed part of the same claim, the Court held that bifurcation was permissible under the Seventh Amendment so long as "the same issue is not reexamined by different juries." *Id.* at 452, quoting *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995); *see also* Fed. R. Civ. P. 42(b) (permitting the Court to "order a separate trial of any claim . . . *or of any separate issue* . . .") Here, as in *Paoli*, there is no Seventh Amendment violation because the first jury

[12] *See also Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1366 n.31 (Fed. Cir. 1998) (recognizing district court's equitable power to enjoin products (vials of antibodies) that had not yet been used in an infringing manner: "Because [the infringer] had used some of its vials in the United States, a clear act of infringement, its propensity to infringe has been sufficiently established such that the court could conclude that enjoining the use of United States-based vials was necessary to prevent infringement.")

determined that the accused Medtronic devices meet the limitations of the claims-in-suit, as properly construed by the Court, whereas the second jury will determine damages, including the timing of Medtronic's sales, which is an entirely separate issue *See Smith v. Alyeska Pipeline Svc. Co.*, 538 F. Supp. 977, 986 (D. Del. 1982).[13]

Finally, Medtronic incorrectly asserts that ACS "invited JMOL" by not presenting evidence at trial on the "timing" of Medtronic's sales. (D.I. 654 at 24-27.) It was Medtronic, however, that failed to raise "timing" as a disputed issue of fact in the Joint Pre-Trial Order. (D.I. 538 at Ex. 2.) Moreover, Medtronic stipulated that, for purposes of the liability trial, the parties would not "present evidence or argument, or elicit any testimony, that relates solely to damages, willfulness, and/or antitrust issues." D.I. 505 at 2. Additionally, Medtronic, like ACS, only addressed "timing" in its *damages* expert reports, not in the expert reports submitted for the liability trial. Having thus agreed to exclude evidence relating to damages, and having joined issue on the question of "timing" only in its *damages* reports, it is disingenuous for Medtronic to now assert that "timing" should have been addressed in the liability trial.

F. Undisputed Evidence Shows That ACS Owns the Lau Patents-in-Suit; Medtronic Produced No Evidence to the Contrary

In yet another hypertechnical "gotcha" argument, Medtronic asserts that ACS lacks Constitutional standing in this case because it failed to prove that it owns the Lau patents-in-suit. That argument is simply untenable, however.

According to Medtronic, because the Lau patents-in-suit stemmed from a continuation-in-part (CIP) application, the assignment of the original '558 application to ACS is insufficient to

[13] Medtronic cites *Alyeska* (D.I. 654 at 24) but ignores its relevant holding, i.e., that bifurcating damages and infringement liability does not violate the Seventh Amendment. While the Court in *Alyeska* pointed out, in *dicta*, that allowing a second jury to determine treble damages would theoretically violate the Seventh Amendment, the Court ultimately determined the issue was moot because treble damages are decided by the Court, not the jury. *Id.* at 986.

show that ACS also owns the four patents-in-suit. (D.I. 654 at 29-30.) Medtronic relies on the MPEP, which states that "[s]ubstitute or continuation-in-part applications require a new assignment if they are to be issued to an assignee." MPEP § 306. Medtronic contends that "this passage [of the MPEP] demonstrates that the Patent Office would not recognize any assignment in a parent application to continue into a CIP application." (D.I. 654 at 30.) That argument, however, ignores the applicable *Federal Circuit* precedent on the issue. *See U. of New Mexico v. Scallen*, 321 F.3d 1111, 1121 (Fed. Cir. 2003) (rejecting an argument that MPEP § 306 legally requires new assignments for CIP applications and holding that section 306 "does not alter the legal ownership rights in patent applications and issued patents.")

At trial, the jury was provided with a copy of each of the four patents-in-suit. Each of those patents clearly lists ACS as the assignee of record on its face. (*See* AX-1, -5, -6, and -7.) Thus, since "the Patent Office would not recognize any assignment in a parent application to continue into a CIP application" (D.I. 654 at 30), the fact that the patents-in-suit were issued, *on their face*, to ACS provides *prima facie* evidence that a new assignment was executed to cover the '154 continuation-in-part application and its progeny. Medtronic produced no evidence to the contrary at trial. Nor could it have, for the assignment of the '790 application (D.I. 623) undisputedly shows that ACS owns each of the four patents-in-suit and, therefore, has standing in this case.[14] Indeed, Medtronic plainly *admitted* ACS's ownership in its proposed jury instructions, stating "ACS is the owner of U.S. Patent No. 5,514,154, U.S. Patent No. 6,066,167, U.S. Patent No. 6,066,168, and U.S. Patent No. 6,432,133." (D.I. 539 at 13.)

[14] Medtronic does not dispute that the assignment to ACS of the '790 application (D.I. 623) proves ownership of the four patents-in-suit. It complains, however, that ACS never presented that particular assignment to the jury. (D.I. 654 at 30.) That point is irrelevant, though, because the *Court*—not the jury—determines Constitutional standing. *See Paradise Creations, Inc. v. U.V Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003). Accordingly, the Court may properly take judicial notice of that assignment to resolve the question of standing.

G. Substantial Evidence Supports the Jury's Verdict That the Lau Claims Are Not Invalid for Obviousness

Obviousness is a question of law based on four factual determinations: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations if present *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). Secondary considerations may include, *inter alia*, commercial success, praise in the industry, long-felt but unresolved need, and failure of others to develop the claimed invention. *Id.* at 17-18. In determining obviousness, the invention must be considered as a whole, not limitation-by-limitation. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) ("In determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed.") (citations omitted). "Throughout the obviousness determination, a patent retains its statutory presumption of validity, see 35 U.S.C. § 282, and the movant retains the burden to show the invalidity of the claims by clear and convincing evidence as to underlying facts." *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1364 (Fed. Cir. 1998).

The validity section of Medtronic's brief is a case study in "revisionist history" or, at the very least, wishful thinking. In either event, the alleged "facts" recited therein bear little resemblance to what actually happened at trial.

To begin with, Medtronic asserts that "both Drs. Saigal and Segal applied" the level of ordinary skill in the art to their analysis in this case. (D.I. 654 at 33.) That is false. Only Dr. Segal—ACS's expert—satisfies the parties' agreed-upon definition of a person of ordinary skill in the art. As explained at trial, Dr. Segal is a practicing interventional cardiologist who has implanted thousands of stents. He is the inventor and patentee of numerous implantable medical

devices and is the current CEO of a medical-device company. In contrast, Professor Saigal—Medtronic's expert—is *not* a person of ordinary skill in the art.[15] (Tr. at 1392-94.) He is neither a physician nor a stent designer, nor does he have any experience designing medical devices generally. (Tr. at 1382-89.) Professor Saigal's education is in *civil* and *aeronautical* engineering (Tr. at 1382), and his professional experiences have largely been on projects far removed from the field of interventional cardiology (Tr. at 1241-42). Because Professor Saigal lacks the requisite experience and expertise in this case, the jury could have reasonably discounted his opinions regarding what a "person of ordinary skill in the art" (which Professor Saigal is not) would have known or done in 1991.

Next, Medtronic contends there was "agreement" among the experts that "the art had been moving in the direction of shorter *elements*, and that those in the art understood that short *elements* could be connected together to avoid migration problems." (D.I. 654 at 32, emphasis added.) Yet ACS's experts, Dr. Kahn and Dr. Segal, never agreed that it was known in the art to connect short "elements" together. Quite the contrary, Dr. Segal testified that the stent community in 1990-91 was focused on stand-alone *stents*, either connected or unconnected, rather than short "elements" that are not in and of themselves stents. (*See* Tr. at 1576-77; *see also* Tr. at 1547-48.)

Regarding the Boneau '331 patent, Medtronic contends that "the central dispute was over whether one skilled in the art would have used connectors to combine the short Boneau elements described in the Boneau '331 patent." (D.I. 654 at 33.) That is an incomplete and misleading summary of the disputed issues at trial. While Dr. Segal did testify that Boneau '331 teaches

[15] The use of "Professor" instead of "Dr." is not meant as a slight to Dr. Saigal. It is meant merely to help keep Dr. Segal and Dr. Saigal—who have very similar names— straight. (*See* Tr. at 1252.) Medtronic's counsel suggested this technique in one of the depositions where the court reporter had trouble differentiating the two experts' names.

away from connecting stents (Tr. at 1558), he also vigorously disputed Professor Saigal's assertion that a person of ordinary skill in the art would read Boneau '331 as teaching the use of 1-2 mm "elements" in the cardiovascular system. (*See, e.g.*, Tr. at 1565-66.) The latter issue was certainly a "central dispute" at trial, though Medtronic fails to mention it in its brief.

Medtronic insists that Dr. Segal agreed that "Mr. Boneau disclosed a structure (a 'thing') that could be made 1mm in length and could expand to diameters effective for the vessels stents normally treat." (D.I. 654 at 38.) Nothing could be further from the truth. While Medtronic provides only a small snippet of Dr. Segal's testimony on that topic, the excerpts below more accurately capture what he said, namely that Boneau '331 does *not* disclose a 1-mm structure:

> Q. All right. So what I'm trying to do, sir, is avoid these definitional problems, so let's, for purposes of my question, I'm not going to call Mr. Bonneau's 1-millimeter structures a stent. But he did describe a physical structure in his patent? You'd agree with me, sir?
>
> A. Sir, my reading of his patent is he describes a stent in his patent and he creates a range. *That does not mean that he discloses something that's 1 millimeter long.* That means he created a range and he talks about stents. *I don't see any 1-millimeter stents actually disclosed in this patent.*
>
> Q. Well, he talks about something being 1 millimeter, doesn't he?
>
> A. *No.* He creates a range and I've seen lots of ranges in patents that don't really refer to anything.

(Tr. at 1641.) The jury reasonably could have credited the testimony of Dr. Segal—an interventional cardiologist who meets the definition of a person of ordinary skill in the art—that Boneau '331 does *not* disclose the use of a 1-mm structure in the coronary anatomy and that a 1-mm structure would not function a stent, as required by the Boneau patent.

Medtronic also asserts that Dr. Segal "essentially agreed with" Professor Saigal's obviousness contentions. (D.I. 654 at 34.) That statement is nothing short of absurd, given that

Dr. Segal flatly *rebutted* each and every one of Professor Saigal's alleged obviousness combinations. (Tr. at 1533, 1570-77.) Dr. Segal testified, for example, that *none* of the five references Professor Saigal relied upon discloses cylindrical elements or a longitudinally flexible stent, as required by all of the asserted Lau claims. (Tr. at 1570-71.) Dr. Segal likewise testified that other required limitations were missing from Professor Saigal's combinations, including projecting edges and non-appreciable shortening ('154 claims), L<D in the unexpanded and uncrimped condition (claim 11 of the '168 patent), and cylindrical elements measuring less than 2.5 mm in length ('133 claims). (Tr. at 1566-67, 1571-72.) Moreover, Dr. Segal testified that there would have been no motivation to connect the stents of Boneau '331—the starting point for all of Professor Saigal's combinations—because Boneau '331 teaches *away* from connecting multiple stents together. (Tr. at 1558, 1572-74.)

Dr. Segal further explained to the jury that Medtronic's obviousness theory contradicts what *actually happened* in the real world. Specifically, whereas Professor Saigal opined (in hindsight) that a person of ordinary skill in the art in 1991 would have known to make Boneau stents so short as to be nonfunctional and then connect those short, nonfunctional structures together, the real-world evidence tells a different story. To begin with, Dr. Stertzer (Boneau's partner) *rejected* the idea of using short 1-2 mm elements because "it became immediately apparent that a device of no more than 1 or 2 millimeters in length would lack the mechanical stability to sustain a coaxial alignment in a hemodynamically active high-pressure coronary vessel." (AX-62, *see also* Tr. at 484-86, 1574-75.) Dr. Stertzer did *not* decide to connect those 1-2 mm rings together to stabilize them, as Medtronic now suggests a person of ordinary skill in the art would have done. (*Id.*) Instead, Dr. Stertzer abandoned the idea of using 1-2 mm rings altogether and opted, instead, to pursue a stand-alone, 4-mm Boneau stent. (*Id.*)

Later, when the engineers at AVE attempted to commercialize the Boneau stent as the "MicroStent PL" in the early 1990's, they continued to pursue the idea of *unconnected stents* rather than connected stents (let alone connected rings). Indeed, even when a prominent Japanese physician suggested, in 1993, connecting the MicroStent PL stents together to prevent migration, AVE's senior engineers continued to resist that idea until, ultimately, the MicroStent PL failed in the marketplace. (AX-61, Tr. at 1588-91.) Thus, the *real world* evidence in this case contradicts Medtronic's hindsight theory that ACS's connected-ring design was "obvious" in 1991. In the end, Medtronic was never able to answer a simple question for the jury. Namely, if ACS's connected-ring design were so obvious in 1991, why didn't anyone else do it?[16]

In addition to rebutting Professor Saigal's alleged obviousness combinations, ACS also presented substantial evidence at trial regarding various "secondary considerations," which constitute objective evidence of non-obviousness. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) ("[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.")

Dr. Segal testified, for instance, that there was a long-felt need in the art for a longitudinally flexible stent with good radial strength. (Tr. at 1578.) Dr. Pearle—an

[16] Though it has *no* explanation for why Dr. Stertzer, Mr. Boneau, and AVE's engineers failed to arrive at the allegedly "obvious" connected-ring design in the early 1990's, Medtronic does speculate as to why Dr. Schatz and the engineers at J&J failed to do so. According to Medtronic's new argument, J&J failed to arrive at the connected-ring design because, while it was known that "shorter and connected stents were desirable" (D.I. 654 at 37), "the Palmaz design could not be made shorter and still work" (*id.*). That simply proves Dr. Segal's point, however. In other words, J&J's engineers could not make a shorter Palmaz design that worked *as a stent*, and they apparently did not think of connecting *cylindrical elements* together to create a connected-ring design. (*See* Tr. at 1575-77.)

interventional cardiologist who testified on behalf of Medtronic—agreed completely with Dr Segal on that point:

> Q So in the 1991 time frame, did interventional cardiologists understand that radial strength and flexibility were both attributes that people were looking for?
> A I think anyone working in this field understood that we needed a stent that had radial strength
> Q And flexibility as well?
> A And flexibility as well. Those were, I think, the two most important features of stents that we were looking for in that time frame.

(Tr. at 715.)

Beverley Huss, former President of Endovascular Solutions at ACS, testified that the Multi-Link design (which practices the claims of the Lau patents, *see* Tr. at 1578-80) was a tremendous commercial success immediately upon its launch:

> Q . . . [W]hat does [AX-1037A] show about Guidant's market share in the same time period?
> A This time frame shows that Guidant took a leadership position very quickly in the coronary stent market with approximately 65-percent market share, about two or three months after the product was FDA approved and released, and held onto that leadership position for many years
> Q Did Guidant consider the Multi-Link to be a commercial success?
> A Absolutely. The Multi-Link was an incredible commercial success.

(Tr. at 1469; *see also id.* at 1580-82.)

Dr. Segal and Dr. Kahn both testified that the Multi-Link stent received copious praise from practitioners in the field for its combination of radial strength and flexibility. (*See* Tr. at 272-74, 1582-84; AX-47, -48, -49.) Indeed, even Dr. Pearle, whom *Medtronic* retained to testify at trial, offered high praise for the Multi-Link stent:

> Q And how would you describe the Multi-Link stents?

A. They were excellent stents for a while. They were the stent I used most frequently. I think they had a better combination of radial strength and flexibility than either the Gianturco/Roubin or the Palmaz/Schatz stent.

Q. Essentially met both of the requirements that you talked with counsel about a few moments ago, that clinicians wanted: Radial strength, longitudinal flexibility; is that right?

A. They were an improvement over previous, not as good as subsequent iterations of even that same stent or others that came along. But in terms of combining those two virtues, they were better than either the Gianturco/Roubin or the Palmaz/Schatz.

(Tr. at 747.)

Finally, Dr. Segal testified that four different companies, J&J, Cook, Medtronic, and AVE, were all trying to achieve a strong yet flexible stent before 1991, yet all failed to develop an acceptable design like the Multi-Link. (Tr. at 1584-89.)

Medtronic did not rebut *any* of these secondary considerations at trial. Indeed, Medtronic's sole validity expert, Professor Saigal, did not even mention secondary factors in his analysis and admitted that his analysis would be "incomplete" if secondary factors were a required consideration:

Q. [I]f the Court were to instruct they jury that you must consider secondary factors all of the time, if they were to do that, then your analysis has been incomplete?

A. So you're saying that that second part be done, regardless of where the first part ended up?

Q. That's correct. If she instructs the Court [sic, jury] that they must consider secondary factors, then you've been deficient in your validity analysis. Would you agree, sir?

A. Then what I've presented to the jury would be incomplete.

(Tr. at 1427.) The fact is, secondary factors *are* a required consideration in a proper obviousness analysis. *See Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000). Tellingly, Medtronic continues to ignore the secondary considerations, even in its renewed JMOL motion.

As thus explained above, there was *substantial* evidence presented at trial—including unrebutted evidence of secondary considerations—upon which the jury reasonably could have based its verdict of nonobviousness That is particularly so in light of Medtronic's high burden of clear and convincing evidence on this issue *See, e.g., NTP, Inc. v. Research in Motion, Ltd.*, 392 F 3d 1336, 1371 (Fed Cir 2004) Indeed, after Medtronic's own interventional cardiologist, Dr Pearle, candidly acknowledged that ACS's connected-ring design was "an improvement" over prior stents, which combined "two virtues" (flexibility and radial strength) "better than either the Gianturco/Roubin or the Palmaz/Schatz," there really is not much room for Medtronic to argue that it is entitled to JMOL on obviousness

V. CONCLUSION

For the reasons set forth above, the Court should deny Medtronic's Renewed Motion for Judgment as a Matter of Law in all respects A proposed Order is attached

Dated: June 17, 2005

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Anne S. Gaza (#4093)
gaza@rlf.com
RICHARD, LAYTON & FINGER
One Rodney Square
P O. Box 551
Wilmington, Delaware 19899
(302) 651-7509

Attorneys for Defendants Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation

Of Counsel:

J Michael Jakes
Gerald F Ivey
Michael A. Morin
FINNEGAN, HENDERSON, FARABOW GARRETT & DUNNER, L L P
901 New York Avenue, N W
Washington, D C 20001-4413
(202) 408-4000

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, Plaintiffs, v MEDTRONIC VASCULAR, INC and MEDTRONIC USA, INC., Defendants	Civil Action No 98-80 (SLR) (Consolidated with C.A No 98-314 (SLR) and C.A No 98-316 (SLR))

ORDER

The Court, having considered Medtronic's Renewed Motion for Judgment as a Matter of Law, and the parties' positions related thereto,

IT IS HEREBY ORDERED this ____ day of _____, 2005 that the Motion is DENIED

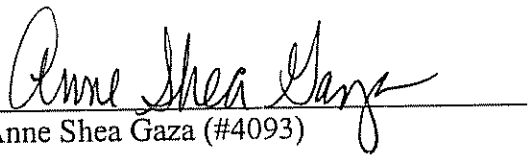
_____
UNITED STATES DISTRICT COURT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing were served this 17th day of June 2005 on counsel in the manner indicated below:

VIA HAND DELIVERY
Karen Jacobs Louden, Esquire
Philip H. Bangle, Esquire
Morris, Nichols, Arsht & Tunnell
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899

VIA FEDERAL EXPRESS
Raphael V. Lupo, Esquire
Donna M. Tanguay, Esquire
Mark G. Davis, Esquire
McDermott, Will & Emery
600 13th Street, N.W
Washington, DC 20005



Anne Shea Gaza (#4093)